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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,987

02/04/2004

Pawan Seth

1259-001/CPB

3583

27572 7590 05/25/2007  
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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

05/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/771,987		SETH ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Melissa Perreira		1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-120 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/3/04, 3/22/07</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification***

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 128 contains the limitations a.) 25 mg colloidal silicon, b.) 39 mg crospovidone and claim 129 contains the limitations a.) 19 mg colloidal silicon, b.) 26 mg polyvinyl alcohol, c.) 30 mg crospovidone, d.) 17 mg glyceryl behenate, e.) 21 mg ethylcellulose, f.) 11 mg polyvinylpyrrolidone which are not provided in the specification. For example p19, [0048] provides for 24.8 mg colloidal silicon dioxide, 39.2 mg crospovidone, etc. and not exactly the amounts recited in the instant claims.

### ***Drawings***

2. The drawings are objected to because figures 3 and 4 recite, "diss lved" on the y-axis. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

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consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

3. Claim 5 is objected to because of the following informalities: the instant claim does not end in a period. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what amount of the coating consists of the water-insoluble, water-permeable film-forming polymer; water-soluble polymer and a plasticizer as the recitation of "consists essentially of" is not clearly defined in the specification.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1,2,6-18,20,22,29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Moeckel et al. (US 5,955,106).

8. Moeckel et al. (US 5,955,106) teaches of an extended release pharmaceutical tablet that contains metformin hydrochloride in about 70-95% (i.e. 850 mg) (column 1, lines 8-13; column 2, lines 23-24), hydrophilic swelling/expanding substances (i.e. polyvinyl alcohol or polyvinylpyrrolidone, hydroxypropyl methylcellulose, etc.) (column 1, lines 20-30), a film former (i.e. ethyl cellulose, methylhydroxypropyl cellulose) (column 1, lines 55-57 and 67; column 2, lines 5-6; column 4, line 2), silicon dioxide and stearic acid (column 2, line 35). The core of the tablet contains the metformin, the expanding substance and magnesium stearate (stearic acid) which is coated with ethyl cellulose via the standard coating process (column 5, lines 13-14; example 1). The controlled release of metformin from the tablets of the disclosure should be over a time period of 0.5-10 hours (column 5, lines 31-33). The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant

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claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile.

9. Claims 1,2,7-13,15,17-19,22,29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (US 6,099,859).

10. Cheng et al. (US 6,099,859) teaches of an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 50-98% or 75-95% (850 mg) (column 3, lines 39 and 66+; column 5, lines 35-41; example 3), a binder (i.e. polyvinylpyrrolidone) in about 0-40% (column 3, lines 40-41 and 48) coated by a semipermeable membrane in about 50-99% (column 4, lines 11,29 and 58). The semipermeable membrane may consist of polymer(s) (i.e. cellulose ethers, hydroxypropyl methylcellulose, polyvinyl alcohol, cellulose acetate, hydroxypropyl cellulose) and a plasticizer (i.e. stearate or dibutylsebacate in about 0-25% (column 4, lines 40 and 61; column 5, line 3; column 6, line 56). The dissolution of the tablet provides for treatment over a twelve to twenty-four hour period (column 2, lines 16-21; column 5, lines 51-57; column 7, lines 13-18). The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile.

11. Claims 1-4,6-14,16-22,28-32,34-42,44-50 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Seth (US 6,350,471B1).

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12. Seth (US 6,350,471B1) teaches of an extended release pharmaceutical tablet that contains a core comprising metformin (column 2, lines 26-28), a lubricant (i.e. stearic acid, glyceryl behenate) (column 1, lines 39-40), a water-soluble binder (i.e. polyvinylalcohol) (column 1, line 44), silicone dioxide (column 3, lines 26-30) and a coating, free of monomeric pore-forming agent, comprising a water-insoluble, water-permeable film-forming polymer (i.e. ethyl cellulose) (column 2, line 35), water-soluble polymer (i.e. polyvinylpyrrolidone, hydroxypropylcellulose) (column 2, lines 41-42) and a plasticizer (i.e. stearic acid, dibutyl sebacate) (column 2, lines 36-40 and 61-63; column 3, lines 31-34). The proportion of water-insoluble polymer, water-permeable film-forming polymer is between 20-85%, the proportion of water-soluble polymer is 10-75% and the proportion of plasticizer is 5-30% (column 2, lines 47-54). The dissolution profile of the tablets free of monomeric pore-forming agent is that after 2 hours from 5-40% of metformin is released, after 4 hours 10-60% is released, after 12 hours 50-98% is released and after 24 hours more than 80% is released (column 3, lines 15-21).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1,2,4-18,20,22-27,29-31,33-46,48,50-55,57-59,61-73,75-81,83,85,87-99,101,103-106 and 108-112 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Moeckel et al. (US 5,955,106) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18<sup>th</sup> Ed. Chpt. 89, p1637.

15. Moeckel et al. (US 5,955,106) teaches of an extended release pharmaceutical tablet that contains metformin hydrochloride in about 70-95% (i.e. 850 mg) (column 1, lines 8-13; column 2, lines 23-24), hydrophilic swelling/expanding substances (i.e. polyvinyl alcohol or polyvinylpyrrolidone, hydroxypropyl methylcellulose, etc.) (column 1, lines 20-30), a film former (i.e. ethyl cellulose, methylhydroxypropyl cellulose) (column 1, lines 55-57 and 67; column 2, lines 5-6; column 4, line 2), silicon dioxide and stearic acid (column 2, line 35). The core of the tablet contains the metformin, the expanding substance and magnesium stearate (stearic acid) which is coated with ethyl cellulose via the standard coating process (column 5, lines 13-14; example 1). The controlled release of metformin from the tablets of the disclosure should be over a time period of 0.5-10 hours (column 5, lines 31-33). Moeckel et al. does not disclose the use of crospovidone or sodium starch glycolate as expanding agent/disintegrant.

16. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovione is a particularly suitable disintegrant (column 3, lines 24-26; column 2, lines 42-43).

17. Remington's Pharmaceutical Sciences **1990** 18<sup>th</sup> Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The



disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

18. The extended release pharmaceutical tablet of the combined disclosures encompass the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

19. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Moeckel et al. for the crospovidone or sodium starch glycolate.

20. Claims 1,2,4,5,7-13,15,17-19,22-27,29-31,33,35-41,43,45-47,50,51-55,57-59,62-68,70,72-74,77-81,83-85,88-94,96,98-100,103-106 and 108-111 are rejected under 35

U.S.C. 103(a) as being unpatentable over Cheng et al. (US 6,099,859) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences 1990 18<sup>th</sup> Ed. Chpt. 89, p1637.

21. Cheng et al. (US 6,099,859) teaches of an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 50-98% or 75-95% (850 mg) (column 3, lines 39 and 66+; column 5, lines 35-41; example 3), a binder (i.e. polyvinylpyrrolidone) in about 0-40% (column 3, lines 40-41 and 48) coated by a semipermeable membrane in about 50-99% (column 4, lines 11,29 and 58). The semipermeable membrane may consist of polymer(s) (i.e. cellulose ethers, hydroxypropyl methylcellulose, polyvinyl alcohol, cellulose acetate, hydroxypropyl cellulose) and a plasticizer (i.e. stearate or dibutylsebacate in about 0-25% (column 4, lines 40 and 61; column 5, line 3; column 6, line 56). The dissolution of the tablet provides for treatment over a twelve to twenty-four hour period (column 2, lines 16-21; column 5, lines 51-57; column 7, lines 13-18). Cheng et al. does not disclose the use of crospovidone or sodium starch glycolate as expanding agent/disintegrant.

22. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovione is particularly suitable for this (column 3, lines 24-26; column 2, lines 42-43).

23. Remington's Pharmaceutical Sciences 1990 18<sup>th</sup> Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The

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disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

24. The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

25. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Cheng et al. for the crospovidone or sodium starch glycolate.

26. Claims 1-14,16-42,44-69,71-95 and 97-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Buhler et al. (US

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6,592,900B1) and/or Remington's Pharmaceutical Sciences 1990 18<sup>th</sup> Ed. Chpt. 89, p1637. 1-4,6-14,16-22,28-32,34-42,44-50 and 56-58

27. Seth (US 6,350,471B1) teaches of an extended release pharmaceutical tablet that contains a core comprising metformin (column 2, lines 26-28), a lubricant (i.e. stearic acid, glyceryl behenate, polyvinylpyrrolidone) (column 1, lines 39-44), a water-soluble binder (i.e. polyvinylalcohol) (column 1, line 44), silicone dioxide (column 3, lines 26-30) and a coating, free of monomeric pore-forming agent, comprising a water-insoluble, water-permeable film-forming polymer (i.e. ethyl cellulose) (column 2, line 35), water-soluble polymer (i.e. polyvinylpyrrolidone, hydroxypropylcellulose) (column 2, lines 41-42) and a plasticizer (i.e. stearic acid, dibutyl sebacate) (column 2, lines 36-40 and 61-63; column 3, lines 31-34). The proportion of water-insoluble polymer, water-permeable film-forming polymer is between 20-85%, the proportion of water-soluble polymer is 10-75% and the proportion of plasticizer is 5-30% (column 2, lines 47-54). The dissolution profile of the tablets free of monomeric pore-forming agent is that after 2 hours from 5-40% of metformin is released, after 4 hours 10-60% is released, after 12 hours 50-98% is released and after 24 hours more than 80% is released (column 3, lines 15-21). Seth does not disclose the use of crospovidone or sodium starch glycolate as expanding agent/disintegrant.

28. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovione is particularly suitable for this (column 3, lines 24-26; column 2, lines 42-43).

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29. Remington's Pharmaceutical Sciences 1990 18<sup>th</sup> Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

30. It is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

31. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Seth for the crospovidone or sodium starch glycolate.

### **Conclusion**

No claims are allowed at this time.

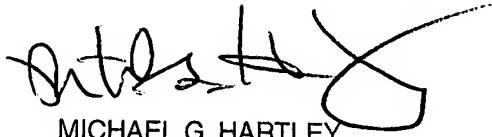
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
May 22, 2007

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER